DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
9 1541d

60 8th Street, N.E.
Atlanta, Georgia 30309

July 16, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Larry Feagin, President
Georgetown Seafood Co., Inc.
P.O. Box 1381
Georgetown, SC 29442

Warning Letter
01-ATL-66

Dear Mr. Feagin:

On November 28-29, 2000, and March 1, 2001, the Food and Drug Administration (FDA) conducted inspections of your plant, located at 1902 Highmarket Street, Georgetown, South Carolina. During those inspections, our investigator documented serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your refrigerated pasteurized crabmeat, fresh shad/roe, and fresh raw shrimp to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at *www.fda.gov.*

The deviations of concern are as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for pasteurized crabmeat to control the food safety hazard of *pathogen growth and toxin formation as a result of time/temperature abuse.*

2. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the "finished product labeling" critical control point (CCP) to control the presence of undeclared sulfites listed in your HACCP plan for fresh raw shrimp.

3. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for scombrotoxic fish (e.g.

shad/roe) lists a critical limit, "50°F or below w/in 6 hrs of death or well-iced," at the "receiving" CCP that is not adequate to control the histamine hazard. The critical limit should include a limit for assessing the results of a sensory examination of a representative sample of the lot of fish received, and a temperature limit for fish delivered after 6 hours of death. In addition, the word "or" in the critical limit should be changed to "and."

4. If you choose to control histamine by insuring that product temperature is below 50°F or is well iced within 6 hours of death, as you have chosen in your HACCP plan, you must have adequate monitoring procedures to comply with 21 CFR 123.6(c)(4). Specifically, you must monitor harvest vessel records for method of capture, date and time of landing, air and water temperatures at time of landing, time of death for fish landed, the method of cooling, time cooling began, storage temperature or adequacy of ice, and the date and time of off-loading. In addition to the harvest vessel record, you should monitor the incidence of decomposition in the lot, and the internal temperature of a representative number of the largest fish (or roe) in the lot at the time of delivery.

5. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the "receiving" CCP to control the histamine hazard listed in your HACCP plan for scombrotoxic fish (e.g. shad/roe).

6. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control records. During our inspection of 11/28-29/00, your firm was unable to provide our investigator with sanitation monitoring records.

7. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor two of the eight areas of sanitation with sufficient frequency to ensure control as evidenced by:

   a. Protection of Food and Food Contact Surfaces from Adulteration - peeling paint and unsealed cinderblock surfaces are present and in direct contact with your ice, and dried fish parts were present on the walls and ceiling of your fish cutting area.

   b. Maintenance of Handwashing/Toilet Facilities - paper towels and soap were not present in the restroom or at the handwashing station.

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter and the FDA 483 issued to you at the end of the November 2000 inspection may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Ballard H. Graham, Director
Atlanta District